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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,701	05/05/1999	CHRISTINE MARIE DEBOUCK	P50572	1155

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EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/07/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/297,701

Applicant(s)

DEBOUCK ET AL.

Examiner

Jehanne Souaya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. Currently claims 1-12 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. This action is NON-FINAL. Response to applicant's arguments follow.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1 and 12 are indefinite in the recitation of "defined materials *derived* from the genomic library" as it is unclear if the recitation is drawn to a genomic DNA library on an array

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or to sequences from genomic DNA that have been changed, for example, mutagenized, in some way.

B) Claims 1 and 12 are indefinite in step h as it is unclear if the primer extension reaction generates the labeled probes.

C) Claims 1 and 12 are indefinite as it is unclear which 'labeled probes' are being referred to. It is noted that the claims lack sufficient antecedent basis for 'the labeled probes generated from the isolated DNA of the test culture'.

D) Claim 12 is indefinite in the recitation of "complemented" in step f as it is unclear if this recitation refers to genes from the genomic library that are responsible for the unaltered phenotype of mutagenized cells or whether it refers to a strand of DNA that is "the complement" of another strand of DNA. Since the specification does not define this term, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 103

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nishi et al (JBC, March 1994, vol. 269, pp 6320-6324) and Quandt et al (Gene, 1993, vol. 127, pp 15-21) in view of Lennon et al (Trends in Genetics, October 1991, vol. 7, pp 314-317).

Nishi et al teaches an agent (LMB) that induces arrest of the eukaryotic cell cycle (abstract, first para of p. 6320). Nishi teaches screening genomic library of LMB-resistant

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mutants to identify the target gene of LMB (abstract, p. 6320, last para). Nishi teaches comparison of allelic mutation and wild-type (p. 6322, col. 2, first full para). Nishi teaches the gene and protein sequence of the LMB resistant gene (p. 6322, Table II). Nishi teaches compositions of the agent LMB (figure 1). Although Nishi does not teach such a method in detecting genes essential to the growth of a single celled organism, one of ordinary skill in the art would recognize that such a method could be used to screen for essential genes in microorganisms. One of ordinary skill in the art would be motivated to screen for essential genes in single celled organisms for the purposes of screening for possible inhibitors of pathogens. Although Nishi does not teach the use of suicide vectors in mutagenizing, Quandt teaches the construction of a set of vector plasmids which greatly facilitate gene replacement and reverse genetics in many Gram-negative bacteria (see abstract). Quandt teaches that these vectors, termed suicide vectors, were used to carry out gene replacement experiments in the *fixN* region of *Rhizobium leguminosarum* (see abstract). Quandt teaches using these vectors in the genetic analysis of a wide range of gram negative bacteria and further teach that these vectors offer a number of improvements on existing *sacB*-based systems which include the ease of cloning fragments into these vectors and the fact that they are mobilisable (see p. 19, col 2 "conclusion"). Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures (see abstract). Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the suicide vectors for the purpose of

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mutagenizing in the modified method of Nishi as Quandt teaches that these vectors are extremely useful in eliminating long and tedious screening procedures.

Although Nishi does not teach the use of arrayed immobilized library to perform the screening of mutants, Lennon et al teach method of screening libraries involving generating a plurality of filters that form a grid, each grid containing at a predefined region, immobilized cDNA clones (page 314, col. 2, first para, page 315, col. 1 last para, and col. 2). Lennon also teaches the use of a “genomic” cDNA library (p. 314, col. 2, last para). Lennon teaches screening the filters with a labeled hybridization probe to, for example, identify cDNAs (equivalent to mRNAs) that are differentially expressed between tissues and/or developmental stages or directly comparing two sets of conditions (Table 1, page 316, col. 2, first full para). Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening methods (p 315, col. 2, last para).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the hybridization based screening method of Lennon to have screened for LMB mutations in a population as taught by Nishi to have obtained the invention as a whole. One of ordinary skill in the art at the time of the invention would have been motivated to have used the methods of Lennon for screening to have screened for LMB target genes as taught by Nishi because Lennon teaches that the use of arrayed libraries can be used to eliminate the need for multiple rounds of clone purification, thereby improving screening

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methods. Thus addition of the method of screening of Lennon to perform the method of Nishi would have made the screening method of Nishi easier to perform.

Response to Arguments

The amendment and response have been thoroughly reviewed but were found unpersuasive. The traversal is on the grounds that Nishi and Quandt in view of Lennon neither teach nor suggest using DNA containing insertional or transposable elements from test cultures as templates for generating specific hybridization probes. This argument was thoroughly reviewed but not found persuasive. Firstly, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, it would be obvious to one of ordinary skill in the art to use a probe that specifically hybridizes to nucleic acids that have been inserted in a larger piece of DNA for the purpose of specifically detecting the presence of the inserted nucleic acid. In addition, the claims as amended are not drawn to probes that have been generated by a primer extension reaction that extends into flanking genomic DNA, such that the probe contains a region that specifically hybridizes to the inserted DNA as well as the flanking genomic DNA. The amendments to claims 1 and 12 do not make clear how the probes are generated. Step h of claim 1, for example, is unclear and appears to missing essential steps. It is unclear how the oligonucleotide probe is related to the primer extension reaction and why

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both are recited in the same step. Further, this step does not make clear that such probes are generated from the test culture DNA. The claims are unclear as to the composition of the oligonucleotide probes, that is, what it specifically targets, and how the probe is generated. For these reasons and the reasons made of record in previous office actions, the rejection under 35 USC 103 over the teachings of Nishi and Quandt in view of Lennon are maintained.

Conclusion

5. No claims are allowable over the cited prior art.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
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June 6, 2002